

The YODA Project Research Proposal Due Diligence Assessment

Part 1: General Information	
YODA Project (Protocol) ID:	2021-4571
Date:	2 February 2021
Product Name:	Bosentan/Macitentan
Therapeutic Area:	Pulmonary Hypertension
Product Class:	Endothelin receptor antagonist
Condition(s) Studied:	Ischemic Digital Ulcers/Idiopathic Pulmonary Fibrosis
Protocol Number(s) and Title(s):	<p>1. NCT00077584 - AC-052-331 - A Randomized, Double-blind, Placebo-controlled, Multi-center Study to Assess the Effect of Bosentan on Healing and Prevention of Ischemic Digital Ulcers in Patients With Systemic Sclerosis</p> <p>2. NCT00903331 - AC-055B201 - A Double-blind, Randomized, Placebo-controlled, Multicenter, Parallel Group Study to Evaluate the Efficacy, Safety, and Tolerability of Macitentan in Patients With Idiopathic Pulmonary Fibrosis</p> <p>3. NCT01474122 - AC-055C302 - Prospective, Randomized, Placebo-controlled, Double-blind, Multicenter, Parallel Group Study to Assess the Efficacy, Safety and Tolerability of Macitentan in Patients With Ischemic Digital Ulcers Associated With Systemic Sclerosis</p>
Part 2: Data Availability	
Question:	Response:
Data Holder has authority to provide clinical trial data or development partner has agreed to share clinical trial data.	Yes
Comments: N/A	
Data Holder has sharable electronic clinical trial data or data can be converted to electronic format.	Yes
Comments: N/A	
De-identification and redaction of clinical trial data in accordance with current HIPAA and EU criteria allows protection of participant privacy and confidentiality.	Yes
Comments: N/A	
The product and relevant indication studied has either been approved by regulators in the US and EU, or terminated from development.	Yes
Comments: N/A	
Data Holder has completed the clinical trial and trial has been completed for a period of at least 18 months (or results published in peer-reviewed biomedical literature).	Yes
Comments: N/A	
Part 3: Data Availability Summary	
Based on the responses to the above Data Availability questions, the requested clinical trial data can be made available for data sharing.	Yes
Part 4: Proposal Review	

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Question:	Response:
Summary-level CSR data is appropriate for the proposed analysis.	No
Participant-level data is appropriate for the proposed analysis.	Yes
A similar analysis is underway or completed/pending disclosure by Janssen.	No
Comments:	